(v) Section 164.512 relating to uses and disclosures for which consent, individual authorization or an opportunity to agree or object is not required, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(vi) Section 164.532 relating to transition requirements; and

(vii) Section 164.534 relating to compliance dates for initial implementation of the privacy standards.

(2) When a health care clearinghouse creates or receives protected health information other than as a business associate of a covered entity, the clearinghouse must comply with all of the standards, requirements, and implementation specifications of this subpart.

(c) The standards, requirements, and implementation specifications of this subpart do not apply to the Department of Defense or to any other federal agency, or non-governmental organization acting on its behalf, when providing health care to overseas foreign national beneficiaries.

EFFECTIVE DATE NOTE: At 67 FR 53266, Aug. 14, 2002, in §164.500, remove ''consent,'' from paragraph (b)(1)(v), effective Oct. 15, 2002.

§ 164.501 Definitions.

As used in this subpart, the following terms have the following meanings:

Correctional institution means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. *Other persons* held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.

Covered functions means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Data aggregation means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

Designated record set means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

Direct treatment relationship means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Disclosure means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions, and any of the following activities of an organized health care arrangement in which the covered entity participates:

(1) Conducting quality assessment and improvement activities, including

outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of §164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) Due diligence in connection with the sale or transfer of assets to a potential successor in interest, if the potential successor in interest is a covered entity or, following completion of the sale or transfer, will become a covered entity; and

(v) Consistent with the applicable requirements of §164.514, creating deidentified health information, fundraising for the benefit of the covered entity, and marketing for which an individual authorization is not required as described in §164.514(e)(2).

Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

Indirect treatment relationship means a relationship between an individual and a health care provider in which:

(1) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

Individual means the person who is the subject of protected health information.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Inmate means a person incarcerated in or otherwise confined to a correctional institution.

Law enforcement official means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to:

(1) Investigate or conduct an official inquiry into a potential violation of law; or

(2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

Marketing means to make a communication about a product or service a purpose of which is to encourage recipients of the communication to purchase or use the product or service.

(1) *Marketing* does not include communications that meet the requirements of paragraph (2) of this definition and that are made by a covered entity:

(i) For the purpose of describing the entities participating in a health care provider network or health plan network, or for the purpose of describing if and the extent to which a product or service (or payment for such product or service) is provided by a covered entity or included in a plan of benefits; or

(ii) That are tailored to the circumstances of a particular individual and the communications are:

(A) Made by a health care provider to an individual as part of the treatment of the individual, and for the purpose of furthering the treatment of that individual; or

(B) Made by a health care provider or health plan to an individual in the course of managing the treatment of that individual, or for the purpose of directing or recommending to that individual alternative treatments, therapies, health care providers, or settings of care.

(2) A communication described in paragraph (1) of this definition is not included in marketing if:

(i) The communication is made orally; or

(ii) The communication is in writing and the covered entity does not receive direct or indirect remuneration from a third party for making the communication.

Organized health care arrangement means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates, and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such

health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Payment means:

(1) The activities undertaken by:

(i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

(ii) A covered health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:

(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider and/or health plan.

Plan sponsor is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in any medium described in the definition of *electronic media* at §162.103 of this subchapter; or

(iii) Transmitted or maintained in any other form or medium.

(2) *Protected health information* excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. 1232g; and

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv).

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. *Psychotherapy notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has

granted authority, that is responsible for public health matters as part of its official mandate.

Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. *Required by law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

EFFECTIVE DATE NOTE: At 67 FR 53266, Aug. 14, 2002, amend §164.501 in the definition of ''health care operations'' by removing from the introductory text of the definition '', and any of the following activities of an organized health care arrangement in which the covered entity participates'' and revising paragraphs (6)(iv) and (v); by removing the definition of ''individually identifiable health information''; by revising the definition of ''marketing''; in paragraph (1)(ii) of the definition of ''payment,'' by removing the word ''covered''; by revising paragraph (2) of the definition of ''protected health information''; by removing the words ''a covered'' and replace them with ''an'' in the definition of ''required by law'', effective Oct. 15, 2002. For the convenience of the user, the revised text is set forth as follows:

§ 164.501 Definitions.

* * * * *

Health care operations means * * *

(6) * * *

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of §164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

* * * * *

Marketing means:

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:

(i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.

(ii) For treatment of the individual; or

(iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

(2) An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

* * * * *

Protected health information means * * *

(2) *Protected health information* excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and

(iii) Employment records held by a covered entity in its role as employer.

* * * * *

§ 164.502 Uses and disclosures of protected health information: general rules.

(a) *Standard.* A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) Pursuant to and in compliance with a consent that complies with § 164.506, to carry out treatment, payment, or health care operations;

(iii) Without consent, if consent is not required under § 164.506(a) and has not been sought under § 164.506(a)(4), to carry out treatment, payment, or health care operations, except with respect to psychotherapy notes;

(iv) Pursuant to and in compliance with a valid authorization under § 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(e), (f), and (g).

(2) *Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by § 164.524 or § 164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subpart.

(b) *Standard: Minimum necessary.* (1) *Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

(2) *Minimum necessary does not apply.* This requirement does not apply to:

(i) Disclosures to or requests by a health care provider for treatment;

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section, as required by paragraph (a)(2)(i) of this section, or pursuant to an authorization under § 164.508, except for authorizations requested by the covered entity under § 164.508(d), (e), or (f);

(iii) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;

(iv) Uses or disclosures that are required by law, as described by § 164.512(a); and

(v) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to § 164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in § 164.522(a).

(d) *Standard: Uses and disclosures of de-identified protected health information.*(1) *Uses and disclosures to create de-identified information.* A covered entity may use protected health information to create information that is not individually identifiable health information or disclose protected health information only to a business associate for such purpose, whether or not the de-identified information is to be used by the covered entity.

(2) *Uses and disclosures of de-identified information.* Health information that meets the standard and implementation specifications for de-identification under § 164.514(a) and (b) is considered not to be individually identifiable health information, *i.e.*, de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of § 164.514, provided that: